**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>BOSTON SCIENTIFIC CORPORATION, Inc.,<br><br>Defendant. | 05 [illegible] RCL<br><br>**Civil Action No.: 05-** |

**COMPLAINT OF THE UNITED STATES**
**UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT**
**21 U.S.C. §§ 301 ET SEQ.**

The United States of America, plaintiff, by Michael J. Sullivan, United States Attorney for the District of Massachusetts, and Peter D. Keisler, Assistant Attorney General, Civil Division, United States Department of Justice, alleges:

1. The United States alleges violations of the Federal Food, Drug, and Cosmetic Act ("the FDCA"), 21 U.S.C. § 331(a), and seeks from defendant Boston Scientific Corporation, Inc. ("Boston Scientific") equitable disgorgement, prejudgment interest, and other statutory and equitable remedies available to this Court.

## JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. This Court has personal jurisdiction over the defendant because, among other things, the defendant's principal place of business is in this District, the defendant transacts business in this District, and the defendant engaged in wrongdoing in this District.

4. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and 1391(c). Defendant transacts business within this District, and acts proscribed by 21 U.S.C. § 331(a) occurred in this District.

## PARTIES

5. Plaintiff is the United States of America on behalf of its agency, the Food and Drug Administration ("FDA"), Department of Health and Human Services.

6. Defendant Boston Scientific has principal offices located in Natick, Massachusetts, within the jurisdiction of this Court. At all relevant times, defendant Boston Scientific was a publicly traded corporation that manufactured and marketed medical devices throughout the United States and internationally. Boston Scientific had an indirect, wholly-owned subsidiary called Scimed Life Systems, Inc. ("Scimed"), which was located in Maple Grove, Minnesota. At all relevant times, Scimed was in the business of manufacturing and distributing various medical devices, including heart catheters and premounted coronary stent delivery systems.

7. At all relevant times, defendant Boston Scientific and its Scimed subsidiary were engaged in manufacturing, packing, storing and introducing into interstate commerce a medical device called the NIR™ ON™ Ranger™ with SOX ("NORS") premounted coronary stent delivery system. Defendant Boston Scientific through its Scimed subsidiary regularly manufactured the NORS from components received in interstate commerce and introduced the NORS into interstate commerce for shipment throughout the United States.

## INTRODUCTION

8. The allegations in this complaint generally address the actions of defendant Boston Scientific, which resulted in the defendant and its Scimed subsidiary shipping 34,589 adulterated and misbranded NORS premounted coronary stent delivery system devices to hospital catheterization laboratories from August 12, 1998, through and including October 5, 1998.

## LEGAL FRAMEWORK

At all times pertinent to this complaint:

9. Pursuant to the FDCA, a company such as the defendant could not deliver or cause to be delivered into interstate commerce a medical device that was adulterated or misbranded. 21 U.S.C. § 331(a).

10. A device under the FDCA included, *inter alia*, any instrument or implant, including any component, part, or accessory, which was either: (1) intended for use in the cure, mitigation, treatment, or prevention of disease in man; or, (2) intended to affect the structure or function of the body. 21 U.S.C. § 321(h). The FDCA further defined devices as being those

articles that did not achieve their primary intended purposes through chemical action within or on the body, and which were not dependent upon being metabolized for achievement of their primary intended purposes. 21 U.S.C. § 321(h).

11. There were three classes of devices under the FDCA. Class III devices were subjected to the highest level of regulation. Class III devices were those: (1) for which general controls and special controls would not provide a reasonable assurance of safety and effectiveness; and (2) which were either for a use in supporting or sustaining human life or for a use which was of substantial importance in preventing impairment of human health, or which presented a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C).

12. Prior to a company marketing a Class III device, that company was required to submit a premarket approval application to the FDA, id., and to provide the FDA with a reasonable assurance that the device was safe and effective for its intended use. 21 U.S.C. § 360e(d)(2); see generally 21 C.F.R. Part 814.

13. Under the FDCA, a device whose quality fell below that which it purported or was represented to possess was deemed adulterated. 21 U.S.C. § 351(c).

14. A device was also deemed adulterated if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation were not in conformity with the applicable requirements set forth in the FDA's Quality System Regulation, 21 C.F.R. Part 820, which was promulgated by the FDA pursuant to 21 U.S.C. § 360j(f)(1).

15. To comply with the Quality System Regulation, a device manufacturer was required, *inter alia*, to establish and maintain adequate procedures to control product that did not

conform to specified requirements (*i.e.*, "nonconforming product"). 21 C.F.R. § 820.90. A manufacturer was also required to implement adequate controls to identify, document, evaluate, segregate, and dispose of nonconforming product, 21 C.F.R. § 820.90(a), and to document any justification for using any nonconforming product, 21 C.F.R. § 820.90(b)(1).

16. The Quality System Regulation also required a manufacturer to establish and maintain adequate corrective and preventive action ("CAPA") procedures, including, *inter alia*, procedures for (1) analyzing sources of quality data to identify existing and potential causes of non-conforming product or other quality problems; (2) verifying or validating CAPA to ensure that it did not adversely affect the finished device; and (3) identifying the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems. 21 C.F.R. § 820.100(a).

17. Under the FDCA, a device was deemed misbranded if its labeling was false or misleading in any particular. 21 U.S.C. § 352(a).

## THE NORS DEVICE

18. The NORS premounted coronary stent with delivery system was a Class III medical device within the meaning of the FDCA.

19. Defendant Boston Scientific through its Scimed subsidiary designed the NORS and developed the manufacturing process for the NORS.

20. The NORS consisted of a balloon catheter, a coronary stent, and elastomeric retaining sleeves called "Sox™" placed over the ends of the crimped stent.

21. Defendant Boston Scientific had a manufacturing partner, located in Israel, that designed and manufactured the stent, called the NIR™. The NIR™ stent was a small stainless steel mesh cylindrical tube that was designed to be implanted in a coronary artery and serve as a scaffolding to help prevent restenosis and/or abrupt reclosure of the coronary artery.

22. Upon receipt of the NIR™ stents at its Scimed subsidiary, defendant Boston Scientific assembled the NORS by crimping the NIR™ stent on a balloon catheter and then sold NORS systems to hospital catheterization laboratories throughout the country.

23. Interventional cardiologists used the NORS in conjunction with a procedure known as percutaneous transluminal coronary angioplasty ("PTCA"). PTCA was intended to open up a blocked coronary artery and restore blood flow to the heart muscle. PTCA consisted of a medical procedure during which an interventional cardiologist threaded a balloon catheter into a patient's coronary artery to the point in the artery where a patient had a blockage or lesion, and then inflated the balloon in an attempt to flatten the material that was clogging the artery and widen the path through which blood could flow to the heart muscle.

24. Thereafter, the interventional cardiologist inserted a premounted coronary stent and delivery system such as the NORS, maneuvered it through the patient's arteries to the lesion site, and inflated the catheter balloon, which simultaneously expanded the diameter of the stent. Once the stent was deployed, the physician deflated the balloon and withdrew the catheter (also known as the delivery system), leaving the stent implanted in the coronary artery to provide arterial support and prevent restenosis and/or abrupt reclosure of the artery at the site of the lesion.

## RATED BURST PRESSURE

25. Premounted coronary stents with delivery systems such as the NORS had a rated burst pressure, which was a critical product specification.

26. Rated burst pressure represented the maximum atmospheric level of inflation to which interventional cardiologists could safely inflate a balloon catheter to deploy a stent without running the risk of a balloon rupture.

27. Defendant Boston Scientific through its Scimed subsidiary listed the rated burst pressure for the NORS devices directly on the device's label and in the directions for use.

28. Defendant Boston Scientific developed internal requirements to ensure that any representations appearing on the NORS' product label were supported by scientific data.

29. To establish rated burst pressure and thereafter make a label claim that the NORS devices had certain specified rated burst pressures, defendant Boston Scientific's Scimed subsidiary established policies requiring the company to conduct testing sufficient to demonstrate that, to a 95% confidence level, 99.9% of all devices would not suffer a leak or burst at or below the specified rated burst pressure.

30. Defendant Boston Scientific knew and understood the importance of rated burst pressure to interventional cardiologists.

31. Defendant Boston Scientific knew and understood that the consequences to a patient resulting from balloon ruptures below rated burst pressure could range from benign to fatal.

32. In marketing materials designed to promote the NORS, defendant Boston Scientific emphasized the NORS' relatively higher rated burst pressures as compared to the rated burst pressure of competitors' products.

33. Absent adequate scientific data to support the rated burst pressure representation on the NORS' label, defendant Boston Scientific knew and understood that the representation would be false and misleading to interventional cardiologists.

## BOSTON SCIENTIFIC'S MANUFACTURING PRACTICES

34. To comply with the Quality System Regulation, defendant Boston Scientific and its Scimed subsidiary knew and understood that they were required to adopt and implement various standard operating procedures.

35. Defendant Boston Scientific and its Scimed subsidiary knew and understood that many of the NORS' performance specifications could only be measured through destructive testing including rated burst pressure.

36. Defendant Boston Scientific further knew and understood that its Scimed subsidiary needed to monitor its manufacturing processes to ensure that after validation the processes continued to produce devices that met all critical performance specifications.

37. Toward that end, defendant Boston Scientific's Scimed subsidiary developed a procedure called Final Functional Testing, which was designed to serve as a spot check or audit of the NORS manufacturing process.

38. The purpose of Final Functional Testing was to allow Boston Scientific and its Scimed subsidiary to verify through a destructive test that the device as manufactured continued

to meet all critical performance specifications and that no problem or defect had been introduced into the device during production.

39. Defendant Boston Scientific's Scimed subsidiary developed a protocol for Final Functional Testing that called for the testing of only two devices manufactured per shift.

40. Defendant Boston Scientific typically manufactured NORS in lots consisting of 10 devices or less, and, on a given shift, often manufactured as many as 100 lots of NORS.

41. Because Final Functional Testing was not a lot or batch release test, Boston Scientific automatically released into finished goods inventory all lots of NORS that were not associated with the individual devices designated for Final Functional Testing.

42. Final Functional Testing consisted of several tests designed to evaluate device performance, one of which was balloon burst testing. The purpose of balloon burst testing was to ensure that the device's balloon did not fail at an atmospheric pressure at or below the rated burst pressure appearing on the device's label.

43. Pursuant to the Final Functional Testing protocol, defendant Boston Scientific conducted balloon burst pressure testing on an every other day basis.

44. If a device failed Final Functional Testing, defendant Boston Scientific's procedures directed that the remainder of the lot associated with the device that failed Final Functional Testing be automatically quarantined and tested.

45. Defendant Boston Scientific's procedures required the company's engineers to conduct an internal investigation to determine the cause of any Final Functional Test failure. The procedures further required that the engineers who reviewed the failures determine whether the

scope of any potential quarantine should be extended beyond the lot associated with the Final Functional Test failure.

## BOSTON SCIENTIFIC'S COMMERCIAL DISTRIBUTION OF THE NORS

46. After receiving FDA approval to market the NORS, defendant Boston Scientific, through its Scimed subsidiary, began shipping the device in interstate commerce on August 12, 1998.

47. Within five days, defendant Boston Scientific began receiving reports from hospitals that the devices' balloons were failing at pressures below the rated burst pressure stated on the device's label. Such failures are often referred to as pinholes or pinhole leaks in the device's balloon (herinafter referred to as "pinholes").

48. These complaints concerned the performance of the delivery system; they did not address the performance of the stents once implanted in patients' bodies. Although many of the reports did not implicate patient safety and the stent was successfully deployed in the patient's artery without complication, a few reports indicated adverse consequences to the patient, including arterial dissections that occurred as a result of the balloon failures.

49. On July 10, 1998 (before commercial launch of the NORS), twice on August 17, 1998, and on August 27, 1998, routine Final Functional balloon burst testing identified four individual NORS devices that failed to meet their labeled rated burst pressure specification.

50. With respect to each of these Final Functional Test failures, defendant Boston Scientific's Scimed subsidiary quarantined the remaining other devices manufactured in the same

lot with the device that had failed, but continued to release into finished goods inventory and ship in interstate commerce all other devices that had been manufactured during the same shift.

51. On August 25, 1998, defendant Boston Scientific initiated a CAPA investigation in response to continued reports from hospitals that the NORS' balloons were failing below their rated burst pressures. As with the earlier complaints, these complaints concerned the performance of the NORS' delivery system, and did not address the performance of the stents once implanted in patients' arteries.

52. On August 28, 1998, as part of the ongoing CAPA investigation, engineers at defendant Boston Scientific's Scimed subsidiary pulled NORS devices from finished goods inventory in an attempt to determine the scope of the problem with the NORS devices.

53. As of August 28, 1998, defendant Boston Scientific had subjected no more than approximately 1.3% of the lots of NORS devices in finished goods inventory to Final Functional balloon burst testing; all other manufactured lots of NORS had been automatically released into finished goods inventory without balloon burst testing any units in those lots.

54. Engineers at defendant Boston Scientific's Scimed subsidiary conducted the balloon burst testing using a protocol that was modeled after the Final Functional Test protocol and that was, in all material aspects, identical to the Final Functional Test protocol.

55. Preliminary testing of the most popular size of the NORS (the 16 mm. x 3.0) on August 28, 1998, revealed that 21.1% of the devices tested (19/90) had balloons that failed below their rated burst pressure.

56. As a direct result of the dramatic and unexpected level of failures, the engineers immediately took steps to shut down manufacture (i.e., crimping) of this size NORS.

57. The engineers promptly communicated the results of the August 28 testing to management at defendant Boston Scientific's Scimed subsidiary, who in turn forwarded the results to management at defendant Boston Scientific.

58. Later that same day (August 28, 1998), Boston Scientific shipped approximately 993 NORS.

59. By August 30, 1998, Scimed engineers completed internal testing of the NORS pulled from finished goods inventory. The results of that testing revealed:

| **DEVICE SIZE** | **PINHOLES OBSERVED** | **TOTAL BALLOON FAILURES** |
|---|---|---|
| NORS 3.0 x 16 | 8.8% pinholes (14/159) | 12.6% failures (20/159) |
| NORS 3.0 x 25 | 2.9% pinholes (3/103) | 4.9% failures (5/103) |
| NORS 3.0 x 32 | 6.0% pinholes (6/100) | 7.0% failures (7/100) |
| NORS 2.5 x 16 | 8.3% pinholes (2/24) | 8.3% failures (2/24) |
| NORS 3.5 x 16 | 6.7% pinholes (2/30) | 6.7% failures (2/30) |
| NORS 4.0 x 16 | 2.9% pinholes (1/34) | 2.9% failures (1/34) |

The Scimed engineers immediately communicated these results to management at both defendant Boston Scientific and its Scimed subsidiary.

60. By not later than August 31, 1998, and in direct response to the results of the internal testing of NORS in finished goods inventory, the Scimed engineers shut down manufacturing (i.e., crimping) on all nine sizes of the NORS then being manufactured. This shutdown included those sizes of the NORS for which internal testing had not yet been conducted.

61. By August 31, 1998, the decision whether to ship the NORS became the responsibility of management at defendant Boston Scientific, who decided to continue commercial distribution of the device.

62. On September 1, 1998, a fifth NORS device failed routine Final Functional balloon burst testing. Defendant Boston Scientific quarantined the other devices manufactured in the same lot as the device that failed. However, defendant Boston Scientific released into finished goods inventory and shipped in interstate commerce all other devices that had been manufactured during the same shift.

63. On September 2, 1998, a Field Action Committee at Boston Scientific determined that the company should continue shipments of the NORS. As of that date, the company had received 39 complaints relating to balloon burst/failure out of an estimated 6,500 devices used (for an estimated complaint rate of 0.6%) and had received reports of 4 devices causing patient injury or complications (for an estimated rate of .05%). Defendant Boston Scientific concluded that "[t]he product failure rate does not represent an unreasonable risk to patient health and is

below the rate estimated for currently marketed competitive product from published data (FDA MDR database)."

64. Between August 30, 1998, and September 16, 1998, defendant Boston Scientific continued to conduct an internal investigation of the NORS, testing devices in finished goods inventory awaiting commercial distribution. This internal balloon burst testing revealed that the NORS in finished goods inventory were continuing to fail at unacceptably high rates.

65. During this time period, defendant Boston Scientific was unable to determine the root cause of the problem and was unable to develop a screening test that could be used during manufacturing to identify all devices that would fail at pressures below the labeled rated burst pressure.

66. During this time period, defendant Boston Scientific was also not able to develop a screening mechanism that could be used to identify those NORS devices already in finished goods inventory that would fail at pressures below rated burst pressure.

67. Despite the company's inability to identify a root cause or to develop a screening test to sort out nonconforming devices, management at defendant Boston Scientific directed that shipments of the NORS continue.

68. Beginning no later than September 9, 1998, defendant Boston Scientific sought and obtained the services of outside legal counsel from whom the company obtained legal advice concerning the NORS. Thereafter, management at defendant Boston Scientific regularly consulted with outside legal counsel on matters relating to the NORS.

69. On September 10, 1998, a prominent interventional cardiologist called individuals in management positions at defendant Boston Scientific and its subsidiary Scimed to advise them that, during a procedure, a NORS balloon had burst at 8 atmospheres, which was significantly below the rated burst pressure for the balloons. The cardiologist urged defendant Boston Scientific to recall the device. The cardiologist warned company officials that the NORS defect could result in devastating complications.

70. On September 13, 1998, a regulatory affairs official at Scimed sent an email to various management employees at defendant Boston Scientific and Scimed advising them that, as of September 10, the company had received 74 complaints relating to below-rated balloon burst failures. According to this email, of the 74 reported complaints, 14 (19%) also involved reports of patient injury. The email further reported that 60 of the complaints concerned balloon failures that occurred during stent deployment.

71. On the afternoon of September 16, 1998, management employees at defendant Boston Scientific unanimously decided that the NORS device needed to be pulled from the market. Although defendant Boston Scientific had received several favorable reports from interventional cardiologists concerning the NORS performance, the company had also received reports from a limited number of prominent physicians raising serious concerns about the device's performance.

72. Internal testing had continued to reveal balloon failures at levels below rated burst pressure, at rates ranging from 1.3% to 8.9%, depending upon the size of NORS tested and inflation medium utilized. Additionally, testing of NORS devices from finished goods inventory

using a handheld inflation device to approximate physician usage resulted in a failure rate of 10.8% (11/102).

73. Despite management's afternoon decision on September 16 to pull the NORS from the market, Boston Scientific shipped 840 NORS later that same day.

74. Also on September 16, 1998, NORS' balloon failures at two hospitals resulted in serious dissections in patients' arteries. As a result, a prominent interventional cardiologist who experienced one of these balloon failures subsequently called a management employee at defendant Boston Scientific's Scimed subsidiary and urged the company to do the right thing and pull the NORS from the market.

75. On September 17, 1998, a management employee at defendant Boston Scientific had a telephone call with representatives from the company's Israeli partner, and explained the company's decision to pull the NORS from the market as follows:

> we analyzed -- uh -- batches of products, hundreds and hundreds and hundreds and hundreds to try to understand what was happening. And what we discovered was that, that we were building into the product – somewhere during the manufacturing process – pinholes, and that these pinholes, the frequency of them -- uh -- was high, in the ten percent range on average. And that that pinhole was in fact a culprit with respect to what was going on in the market -- uh -- with physicians who were using the device as intended, as it was -- as indicated. Furthermore -- uh -- when we analyzed this -- uh, uh -- and didn't believe it and, and, and, and drilled down further and further, we came yesterday, to the, uh, kind of an incontrovertible position here, that we have this embedded problem in our inventory and in our current manufacturing process -- uh -- and that we are producing product that does not meet the label spec or does not meet the standard -- uh -- against which this product was reviewed and approved. So even though, even though the outcome in the market is very, very good – in fact better than our competitors – uh, we're agonizing over this because, in spite of that, we still find ourselves in a situation where we're in violation of the Code and we're in fact shipping adulterated product and we cannot do that.

76. During that same conversation, the same management employee at defendant Boston Scientific further explained why the company believed it needed to pull the NORS from the market:

> ... That's the problem and we don't want to recall it, but I don't think we have any alternative than – but to not recall but withdraw it – uh ... because in fact we're shipping product ... that does not meet spec. And, and that's a fine line, I know, but it is not arguable that it doesn't meet the spec, and it is not arguable that if it doesn't meet the spec that we have to have some reason to be -- eh, to continue shipping it that right now I don't understand or know about.... [O]utside counsel ... who is very expert on these matters -- has, has advised us that in fact -- uh -- we are thinking about this properly and that the issue is not one of safety – that is simply not the issue here – the issue is an internal issue of our manufacturing process failing to produce a product that meets spec which we therefore don't feel we can ship.

77. Thereafter, during that same September 17 conference call, defendant Boston Scientific changed course and determined that it would consult with regulatory officials at the FDA prior to pulling the NORS from the market. Outside legal counsel, who was participating on the call and who had heard the statements quoted in paragraphs 75–76 above, advised upper management employee at defendant Boston Scientific that "this approach is one that I believe will satisfy our regulatory interests."

78. On September 17, 1998, defendant Boston Scientific, after consulting with outside legal counsel, began sending a "Dear Doctor" letter to interventional cardiologists throughout the country informing physicians that the company had "received reports of balloon failures" with respect to the NORS and reminding physicians to adhere to the device's instructions for use. The letter, however, made no reference of the fact that the company's internal testing had revealed that there was a defect in the device.

79. On September 18, 1998, outside legal counsel contacted an official at the FDA and scheduled a conference call for September 21, 1998, during which defendant Boston Scientific and the FDA would discuss the NORS situation.

80. Prior to the September 21 conference call with the FDA -- and despite its conclusion that the NORS was "adulterated" and "misbranded" and needed to be pulled from the market -- defendant Boston Scientific continued shipping the NORS in interstate commerce, shipping 868 units on September 17, 1998, and shipping 754 units on September 18, 1998.

81. As of the September 21 conference call with the FDA, defendant Boston Scientific had received 100 complaints concerning NORS' balloon failures at below the rated burst pressure, out of an estimated 20,000 NORS devices that had been used in surgical procedures (for an estimated complaint rate of 0.5%). Of the 100 complaints received as of that date, 18 were associated with procedural complications (0.09%). All of the complaints continued to be limited to the performance of the NORS' delivery system; they did not implicate the stents' performance once implanted in patients' arteries.

82. On September 21, 1998, representatives from defendant Boston Scientific participated in a conference call with representatives from the FDA during which the parties discussed various issues concerning the NORS' performance. Also on the call were defendant Boston Scientific's outside legal counsel and an interventional cardiologist who was serving as the company's informal medical advisor with respect to the NORS.

83. During the September 21 conference call with the FDA, representatives from the FDA discussed various matters, including the NORS' field performance, the reported complaints

associated with the NORS' delivery system, the severity (or lack thereof) of the complaints with respect to patient safety, the fact that the stents' performance once implanted in patients' arteries was not implicated by the problem, and the fact that the company was continuing to ship NORS from finished goods inventory despite not knowing the cause of the problem and despite not having developed a test procedure to screen defective devices prior to shipment.

84. After the September 21 FDA conference call, defendant Boston Scientific continued shipping the NORS from finished goods inventory. These shipments persisted even after an FDA official on at least two different occasions advised a management employee at defendant Boston Scientific that the FDA was concerned about and "very uncomfortable " with the company's continued shipments of the device.

85. On September 30, defendant Boston Scientific sent to the FDA via facsimile a Health Hazard Assessment, which stated that "[g]iven the low field occurrence rate and low probability of patient injury, a decision was made to not take any field action at this time but to aggressively continue the engineering investigation of the manufacturing processes and product, and increase communication to the physicians using the product." This document indicated that there had been 123 complaints related to NORS' balloon failures out of an estimated 25,000 devices used (for an estimated complaint rate of .49%), that 18 of those complaints resulted in patient injuries, that one was associated with a death, and that the estimated complaint and injury rates for the NORS was comparable to the rates associated with the NORS' competitors' devices.

86. Very early in the morning of October 2, 1998, the interventional cardiologist who was serving as defendant Boston Scientific's informal medical advisor with respect to the NORS

sent an email to a management employee at defendant Boston Scientific's subsidiary expressing renewed concerns with respect to the NORS' performance and warned that "[e]ven an occasional adverse event which is unpredictable and clearly related to manufacturing flaws may be too damaging to tolerate." Later that morning, the Scimed official who received this email forwarded it to various management employees at defendant Boston Scientific. Later that day, defendant Boston Scientific shipped an additional 841 NORS devices to hospitals throughout the country.

87. On October 5, 1998, defendant Boston Scientific -- having been unsuccessful at determining the root cause of the problem and having been unable to develop a successful screening test that would identify all NORS that would fail at pressures below rated burst pressure -- informed the FDA that the company was immediately stopping shipments of the NORS and pulling the product from the market. Nevertheless, later that day, Boston Scientific shipped an additional 833 NORS to hospitals throughout the country.

88. Shortly thereafter, Boston Scientific commenced a voluntary recall of the NORS.

89. From August 12, 1998, when it commenced shipping the NORS through October 6, 1998, when it stopped shipping the NORS, defendant Boston Scientific shipped 34,589 NORS to hospital catheterization laboratories. As part of the recall, hospital catheterization laboratories returned 8,809 NORS to defendant Boston Scientific.

## COUNT ONE

### Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a) (Interstate Shipments of Adulterated Medical Devices)

90. Plaintiff realleges and incorporates herein by reference each and every allegation set forth in paragraphs 1 through 89.

91. Defendant Boston Scientific violated 21 U.S.C. § 331(a) by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, adulterated devices -- namely, NORS premounted coronary stent with delivery systems. These devices were adulterated within the meaning of 21 U.S.C. § 351(c) in that the quality of the devices (namely, the rated burst pressure of the NORS' delivery systems' balloons) fell below that which was represented on the NORS' labels. These devices were also adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for the manufacture, packing, storage and installation of the NORS did not conform with the Quality System Regulation, 21 C.F.R. Part 820, namely:

(a) Defendant Boston Scientific failed to control nonconforming product by not adequately establishing and maintaining adequate procedures to identify, document, evaluate, segregate, and dispose of non-conforming product, and by failing to justify for use of nonconforming product, in violation of 21 C.F.R. § 820.90; and

(b) Defendant Boston Scientific failed to adequately establish and maintain adequate corrective and preventive action ("CAPA") procedures, including, but not limited to, procedures for analyzing sources of quality data to identify existing and potential causes of non-conforming product and other quality problems, in violation of 21 C.F.R. § 820.100(a)(1).

92. Through its illegal distribution of adulterated medical devices, defendant Boston Scientific was unjustly enriched and obtained ill-gotten gains, including revenues and profits, to which it was not lawfully entitled.

93. By this claim, the United States requests a full accounting of all revenues and profits (and interest thereon) from defendant Boston Scientific and disgorgement of all profits and ill-gotten gains.

## COUNT TWO

### Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a) (Interstate Shipments of Misbranded Medical Devices)

94. Plaintiff realleges and incorporates herein by reference each and every allegation set forth in paragraphs 1 through 93.

95. Defendant Boston Scientific violated 21 U.S.C. § 331(a) by introducing and causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, misbranded devices – namely NORS premounted coronary stent with delivery systems that were misbranded within the meaning of 21 U.S.C. § 352(a), in that the NORS' labeling falsely and misleadingly stated incorrect burst pressure for the devices' balloons.

96. Through its illegal distribution of misbranded medical devices, defendant Boston Scientific was unjustly enriched and obtained ill-gotten gains, including revenues and profits, to which it was not lawfully entitled.

97. By this claim, the United States requests a full accounting of all revenues and profits (and interest thereon) from defendant Boston Scientific and disgorgement of all profits and ill-gotten gains.

**REQUEST FOR RELIEF**

WHEREFORE, the United States demands and prays that this Court enter an Order and Judgment in favor of the United States and against the defendant as follows:

1. On Counts One and Two, requiring an accounting and disgorgement of all ill-gotten gains and profits (with prejudgment interest) that defendant Boston Scientific obtained as a result of its delivering for introduction into interstate commerce adulterated and misbranded medical devices; and

2. Awarding the plaintiff costs and granting such other statutory and equitable relief as this Court deems just and proper.

DATED this 24th day of June, 2005.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

Suffolk, ss.

Boston, Massachusetts
DATE: June 24, 2005

I, Anton P. Giedt, Assistant U.S. Attorney, do hereby certify that I have this day served a copy of the foregoing upon the Plaintiffs' counsel of record in accordance with Fed. R. Civ. P 4 by hand and electronically.

/s/ Anton P. Giedt
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